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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,652	CHALLITA-EID ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7,9-13,15,70 and 78-88* is/are pending in the application.

4a) Of the above claim(s) *15,70 and 84-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7,9-13 and 78-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-7, 9-13, 15, 70, and 78-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 28 February 2005 has been entered in full. Claims 4-7, 9-13, and 78-83 are amended. Claims 1-3, 8, 14, 16-69, 71-77 are cancelled.

This application contains claims 15, 70, and 84-88 drawn to an invention nonelected without traverse in the response of 19 July 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-7, 9-13, and 78-83 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objections to the specification at pg 3-4 of the previous Office Action (02 December 2004) are *withdrawn* in view of the amended specification (hyperlinks and Brief Description of the Drawings) and title (28 February 2005).

2. The objection to claims 4, 11, 12 at pg 4 of the previous Office Action (02 December 2004) is *withdrawn* in view of the amended claims (28 February 2005).

3. The rejection of claims 4 and 9 under 35 U.S.C. § 101 ("product of nature") as set forth at pg 4-5 of the previous Office Action (02 December 2004) is *withdrawn* in view of the amended claims (28 February 2005).

4. The rejection of claims 4-7, 9-13, and 78-83 under 35 U.S.C. § 112, first paragraph (enablement) as set forth at pg 8-14 of the previous Office Action (02 December 2004) is

withdrawn in part in view of the amended claims (which no longer recite % identity language) (28 February 2005). See section on 35 U.S.C. § 112, first paragraph, below.

5. The rejection of claims 4-7, 9-13, and 78-83 under 35 U.S.C. § 112, first paragraph (written description) as set forth at pg 14-17 of the previous Office Action (02 December 2004) is *withdrawn* in view of the amended claims (28 February 2005).

6. The rejections of claims 4-7, 9-13, and 78-83 under 35 U.S.C. § 112, second paragraph as set forth at pg 17 of the previous Office Action (02 December 2004) are *withdrawn* in view of the amended claims (28 February 2005).

Sequence Compliance

7. The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (28 February 2005) has been considered and is found persuasive. Therefore, the requirements set forth in the Notice to Comply (02 December 2004) are withdrawn.

Claim Rejections - 35 USC § 101 and 35 § USC 112, first paragraph

8. Claims 4-7, 9-13, and 78-83 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for claims 4-7, 9-13, and 78-83 at pg 4-8 of the previous Office Action of 02 December 2004.

Specifically, claims 4-7, 9-13, and 78-83 are directed to an antibody or fragment that specifically binds to a protein having an amino acid sequence of SEQ ID NO: 2570. The claims also recite that the antibody is a monoclonal antibody and that the monoclonal antibody is

recombinantly produced. The claims recite that the antibody or fragment may be labeled with a detectable marker or an agent. The claims recite a non-human transgenic animal that produces an antibody that specifically binds to a protein having the amino acid sequence of SEQ ID NO: 2570. The claims recite a hybridoma that produces an antibody that specifically binds to a protein having an amino acid sequence of SEQ ID NO: 2570.

Applicant's arguments (28 February 2005), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Applicant asserts that the claimed invention is supported by a well-established utility. Applicant argues that the claimed subject matter is useful to detect or treat a cancer that expresses the 108P5H8 gene. Applicant explains that the specification shows SEQ ID NO: 2570 is expressed in prostate cancer. Applicant contends that the specification clearly teaches that the 108P5H8 polypeptide is useful as a marker for cancer. Applicant adds that antibodies specific for the 108P5H8 polypeptide can be used to detect prostate cancer. Applicant asserts that it is inconsequential that the biochemical function of the 108P5H8 polypeptide is not emphasized in the specification because the invention is not directed to that subject matter. Applicant submits that not every antibody will bind to a 108P5H8-expressing cancer cell.

Applicant's arguments have been fully considered but are not found to be persuasive. Although Applicant asserts that SEQ ID NO: 2570 is expressed in prostate cancer, 108P5H8 mRNA is also expressed in several normal tissues (including prostate) and other cancer tissues/cell lines (pg 11; pg 77; Figures 11 and 14; *especially Figures 11B(lane 3) and 11C*). The 108P5H8 mRNA is not specific to one tissue and the specification discloses nothing about the normal level of expression of the 108P5H8 polypeptide. The specification does not disclose

any specific cancers that are associated with altered levels or forms of the 108P5H8 polypeptide. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Also, evidence of mere expression in a tissue is not tantamount to showing a functional role of the 108P5H8 polypeptide.

As discussed in the previous Office Action of 02 December 2004, Haynes et al. (1998, Electrophoresis, 19: 1862-1871), teaches that polypeptide levels cannot be accurately predicted from mRNA levels, and that, according to their results, the ratio varies from zero to 50-fold (page 1863). The literature cautions researchers against drawing conclusions based on small changes in transcript expression levels between normal and cancerous tissue. For example, Hu et al. (Journal of Proteome Research 2: 405-412, 2003) analyzed 2286 genes that showed a greater than 1-fold difference in mean expression level between breast cancer samples and normal samples in a microarray (pg 408, middle of right column). Hu et al. discovered that, for genes displaying a 5-fold change or less in tumors compared to normal, there was no evidence of a correlation between altered gene expression and a known role in the disease. However, among genes with a 10-fold or more change in expression level, there was a strong and significant correlation between expression level and a published role in the disease (see discussion section). Similarly, Chen et al. (2002, Molecular and Cellular Proteomics 1: 304-313) disclose that twenty-eight of the 165 protein blots (17%) or 21 of 98 genes (21.4%) had a statistically significant correlation between protein and mRNA expression (see Abstract and Table I). In addition, their results showed that no significant correlation between mRNA and protein expression was found ($r = -0.025$), if the average levels of mRNA or protein among all samples were applied across the 165 protein blots (98 genes). The reference also teaches that the

mRNA/protein correlation coefficient varied among proteins with multiple isoforms, indicating potentially separate isoform-specific mechanisms for the regulation of protein abundance. In this study using a quantitative analysis of mRNA and protein expression within the same lung adenocarcinomas, it is showed that only a minority subset of the proteins exhibited a significant positive correlation with mRNA abundance.

It is clear from the instant specification that the 108P5H8 polypeptide described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this DNA, protein, and antibody may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. As discussed in Brenner v. Manson, (1966, 383 U.S. 519, 148 USPQ 689), the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and,
> "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Accordingly, the specification's assertions that the 108P5H8 polypeptide and antibody have utility in the fields of cancer diagnostics and cancer therapeutics are not substantial.

(ii) Applicant states that the 108P5H8 polypeptide is expressed in normal and cancerous prostate. Applicant asserts that this observation is not relevant to the use of this protein as a

target for immunotherapy. Applicant indicates that such expression could easily contribute to the efficacy of the antibody, in that it would be even more likely to bind a 108P5H8-expressing cancer, such as prostate cancer. Applicant submits that the more copies of 108P5H8 on a target, the more likely an antibody against 108P5H8 would be to find the target.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, since 108P5H8 mRNA is expressed in normal prostate and cancerous prostate tissue (see Figure 11B (lane 3) and Figure 11C), the asserted utility of detecting or treating a cancer that expresses the 108P5H8 gene is not credible, specific and substantial ("real-world") asserted utility or a well-established utility. For example, if 108P5H8 is expressed in both normal prostate and cancer prostate, one skilled in the art cannot detect or treat prostate cancer in a patient. The skilled artisan cannot determine which patient has cancer and which patient does not. The specification does not disclose any specific cancers that are associated with altered levels or forms of the 108P5H8 polypeptide as compared to normal tissues. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Also, evidence of mere expression in a tissue is not tantamount to showing a functional role of the 108P5H8 polypeptide.

It must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of

enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

(iii) Applicant asserts that contrary to the position taken by the Office, the central dogma of molecular biology still holds that overexpression of mRNA is a valid indicator of protein overexpression. Applicant states that this principle of molecular biology remains valid, notwithstanding the nearly seven year old observations made in Haynes et al.

Applicant's arguments have been fully considered but are not found to be persuasive. Haynes et al. teaches that polypeptide levels cannot be accurately predicted from mRNA levels. Although Haynes was published 7 years ago, current literature still cautions researchers from drawing conclusions based on small changes in transcript expression levels between normal and cancerous tissue (see for example, Hu et al. (2003) and Chen et al. (2002)).

In conclusion, the 108P5H8 polypeptide, and antibody of the instant application (SEQ ID NO: 2570) are not supported by either a credible, specific and substantial ("real-world") asserted utility or a well-established utility. The polypeptide, and antibody do not have a substantial utility because basic research is required to study the properties and activity of the polypeptide of SEQ ID NO: 2570. Until some actual and specific significance can be attributed to the protein identified in the specification as 108P5H8, the instant invention is incomplete. In the absence of knowledge of the biological significance of this protein, there is no immediately obvious patentable use for it. If the specification discloses nothing specific and substantial about the 108P5H8 polypeptide, therefore both the polypeptide and its antibodies have no patentable

utilities. Since the instant specification does not disclose a "real world" use for 108P5H8 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

9. Claims 4-7, 9-13, and 78-83 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for claims 4-7, 9-13, and 78-83 at pg 8 of the previous Office Action (02 December 2004).

Since Applicant has not provided evidence to demonstrate that the 108P5H8 polypeptide has a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. It is noted that the instant specification is required to teach one skilled in the art how to make and use the claimed polypeptide and antibody.

9a. However, even if the claimed invention is eventually deemed to have a credible, specific and substantial asserted utility or a well established utility, claims 11 and 78-83 would remain rejected under 35 U.S.C. § 112, first paragraph. The basis for the following issues is set forth at pg 10-14 of the previous Office Action (02 December 2004).

Claims 11 and 78-83 are directed to a non-transgenic animal that produces an antibody and an antibody or fragment that specifically binds to a protein having an amino acid sequence of SEQ ID NO: 2570, wherein the antibody or fragment is labeled with a diagnostic agent or a

cytotoxic agent. Furthermore, the claims recite that the cytotoxic agent is selected from the group consisting of radioactive isotopes, chemotherapeutic agents, and toxins.

(i) Applicant asserts at pg 17 of the response of 28 February 2005 that those of ordinary skill in the art are well versed in the production and labeling of antibodies. Applicant argues that an applicant for a patent need not and preferably will not disclose that which is already well known in the art.

Applicant's arguments have been fully considered but are not found to be persuasive. In the previous Office Action, the Examiner did not raise the issue of undue experimentation in the production and labeling of antibodies. Specifically, the Examiner indicated that she had interpreted the phrases "diagnostic agent" and "cytotoxic agent" as intended uses of the antibody. As discussed in the previous Office Action, the specification of the instant application does not disclose any methods or working examples that indicate labeled anti-108P5H8 antibodies or fragments thereof diagnose a disease or are cytotoxic. Undue experimentation would be required of the skilled artisan to determine the optimal quantity, duration, and route of administration of an anti-108P5H8 antibody labeled with a diagnostic agent or a cytotoxic agent. There is little or no guidance in the specification indicating what specific tissues, cells, or cancers are being targeted by the labeled anti-108P5H8 antibody. The specification does not disclose a correlation between a specific disease state and an alteration in expression level, form, temporal pattern, etc. of the 108P5H8 polypeptide. Significant further experimentation would be required of the skilled artisan to identify individuals with a disease involving the 108P5H8 polypeptide. Although the specification outlines a prophetic example of administration of an anti-108P5H8 antibody (pg 63, for instance), this is not adequate guidance, but is merely an invitation to the

artisan to use the current invention as a starting point for further experimentation. Such trial and error experimentation is considered undue. Administration of the antibody is unpredictable because the skilled artisan is not able to determine the effect the antibody in the subject. More specifically, the present invention is unpredictable and complex wherein one skilled in the art may not necessarily diagnose or treat a disease by administration of a labeled anti-108P5H8 antibody. As discussed in the previous Office Action, relevant literature teaches that problems are often encountered in the effort to use antibodies, including monoclonal antibodies, as clinical reagents. A few of these problems include: the human immune response to foreign antibodies, low affinity or nonoptimal systemic half-life of antibodies, dose and schedule of administration, expression of antigen on normal tissue, and difficulty in producing sufficient quantities of antibody for therapy, among others (Moore, Clin. Chem 35: 1849-1853, 1989 ; Dillman et al., Cancer Invest 19(8): 833-841, 2001, Table 3). Dillman et al. also teaches that if used for a therapeutic application, for example, monoclonal antibodies are tumor-specific and there is always the potential toxicity against normal tissues (Dillman et al., pg 836, col 2, 2nd full paragraph). Dillman et al. indicates that major toxicities associated with immunoconjugates relate to the cytotoxicity of the substance that is attached and the expression of the tumor-associated antigen on normal tissue (pg 837, col 1, 1st full paragraph). Clinical trials of chemotherapy-antibody conjugates have been discontinued because of significant toxicity resulting from reactions with antigen on normal cells in the gastrointestinal tract and brain (Dillman et al. pg 837, col 1, 1st full paragraph).

9b. It is noted that specific issues of claim 11, which is directed to a non-human transgenic animal, were discussed under 35 U.S.C. § 112, first paragraph, at pg 10-12 of the previous Office Action (02 December 2004). However, Applicant did not specifically address the Examiner's issues in the response of 28 February 2005. The Examiner maintains the rejection for reasons already made of record (and also reiterated below).

The specification of the instant application discloses that nucleic acids that encode a 108P5H8 protein can be used to generate either transgenic animals or "knock out" animals that, in turn, are useful in the development and screening of therapeutically useful reagents (the bottom of pg 36 through pg 37). The specification teaches that embryonic stem cells or other types of embryonal cells can be transfected *in vitro* with a DNA vector capable of homologously recombining into the genome, injected into a blastocyst, and implanted into a pseudopregnant female animal resulting in progeny with transgenic DNA inserted into one or more copies of the targeted gene of interest. However, there are no methods or working examples disclosed in the instant application whereby a multicellular animal with the incorporated 108P5H8 gene is demonstrated to express the 108P5H8 peptide. There are also no methods or working examples in the specification indicating that a multicellular animal has the 108P5H8 gene "knocked out". The unpredictability of the art is *very high* with regards to making transgenic animals. For example, Wang et al. (Nuc. Acids Res. 27: 4609-4618, 1999; pg 4617) surveyed gene expression in transgenic animals and found in each experimental animal with a single "knock-in" gene, multiple changes in genes and protein products, often many of which were unrelated to the original gene. Likewise, Kaufman et al (Blood 94: 3178-3184, 1999) found transgene expression levels in their transfected animals varied from "full" (9 %) to "intermediate" to "none" due to

factors such as "vector poisoning" and spontaneous structural rearrangements (pg 3180, col 1, 2nd full paragraph; pg 3182-3183). Additionally, the specification does not provide guidance for identifying and isolating embryonic stem cells from species other than mouse, or for identifying other embryonal cells which are capable of contributing to the germline of any animal. At the time of filing, Campbell et al. teaches that, "in species other than the mouse the isolation of ES cells has proved more difficult. There are reports of ES-like cell lines in a number of species...However, as yet there are not reports of any cell lines which contribute to the germ line in any species other than mouse" (Campbell et al. Theriology 47(1): 63-72; see pg 65, 2nd paragraph). Thus, based on the art recognized unpredictability of isolating and using embryonic stem cells or other embryonal cells from animals other than mice to produce transgenic animals, and in view of the lack of guidance provided by the specification for identifying and isolating embryonal cells which can contribute to the germ line of any non-human mammal other than the mouse, such as dogs or cows, the skilled artisan would not have had a reasonable expectation of success in generating any and all non-human transgenic animals using ES cell technology.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to generate a transgenic animal expressing the 108P5H8 protein and to determine the optimal quantity, duration, and route of administration of an anti-108P5H8 antibody labeled with a diagnostic agent or cytotoxic agent and to diagnose or treat a disease by administration of a labeled anti-108P5H8 antibody; the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to the same; the complex nature of the invention; and the state of the prior art

which establishes the unpredictability of making transgenic animals and the unpredictability of the effects of monoclonal antibodies *in vivo,* undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Priority

Applicant's claim for priority under 35 U.S.C. 119(e) is acknowledged. Therefore, the filing date of 15 December 2000 has been used for the purposes of applying the prior art below.

Claim Rejections - 35 USC § 102

10. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Murgia et al. (Am J Physiol (Gastrointest Liver Physiol) 40: G1231-G1239, 1999). The basis for this rejection is set forth for claim 4 at pg 18 of the previous Office Action (02 December 2004).

Applicant asserts that to be anticipatory, a reference must teach or suggest each and every limitation of the claimed invention and cites *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Applicant indicates that pending claim 4 recites an isolated antibody or antibody fragment that specifically binds to a protein having an amino acid sequence of SEQ ID NO: 2570. Applicant argues that Murgia et al. only teaches a sequence that has 91.2% sequence identity to SEQ ID NO: 2570, therefore the cited reference does not teach each and every limitation of the claimed invention, it does not anticipate claim 4.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the fact patterns of the case cited by the Applicant and of the instant rejection are significantly different, and the court decision is not binding with regard to the instant rejection. Furthermore, as discussed in the previous Office Action, Murgia et al. teach a polyclonal antibody that was raised in rabbit against a synthetic 14 amino acid peptide spanning residues

370-383 of their Dri 27 sequence, which corresponds to amino acids 369-384 of SEQ ID NO: 2570 of the instant application (see sequence alignment attached to previous Office Action as Appendix A; Murgia et al., pg G1232; Figure 2). Therefore, the antibody of Murgia et al. will bind to the isolated protein of SEQ ID NO: 2570 of the instant application.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

BEB
Art Unit 1647
04 May 2005

ELIZABETH KEMMERER
PRIMARY EXAMINER